

N08C7: A Phase III, Randomized, Placebo-controlled, Double-Blind Trial of Flaxseed for the Treatment of Hot Flashes

Fast Facts

Flaxseed bars/placebo bars provided

Inclusion Criteria

1. ≥ 18 years of age.
2. Women with a history of breast cancer or other cancer (currently without malignant disease) or women who have no history of breast cancer but who wish to avoid estrogen due to a perceived increased risk of breast cancer.
3. Bothering hot flashes (defined by their occurrence ≥ 28 times per week and of sufficient severity to make the patient desire therapeutic intervention).
4. Women who are postmenopausal as defined by (1) absence of a period in the past 12 months; or (2) bilateral oophorectomy. Note: Women with at least one ovary but without a uterus should be deemed postmenopausal by either (1) age over 55 or (2) a combination of estrogen within a postmenopausal range (per local lab) and FSH over 40 mIU/mL.
5. Presence of hot flashes for ≥ 1 month prior to randomization.
6. Life expectancy > 6 months.
7. ECOG Performance Status (PS) 0 or 1
8. Ability to complete questionnaire(s) by themselves or with assistance.
9. Provide informed written consent.

Exclusion Criteria

1. Any of the following current (≤ 4 weeks) or planned therapies (EXCEPTION: tamoxifen, raloxifene, or aromatase inhibitors are allowed, but the patient must have been on a constant dose for ≥ 4 weeks and must not be expected to stop the medication during the study period):
 - Androgens
 - Estrogens
 - Progestational agents
2. History of allergic or other adverse reaction to flaxseed.
3. Current (≤ 7 days prior to registration) or planned use of other agents for treating hot flashes (i.e.: gabapentin, clonidine, antidepressants) except stable dose of vitamin E (as a general vitamin supplement), if no more than 800 IU/day, is allowed as long as it was started > 30 days prior to study initiation and is to be continued through the study period. Women who have been using antidepressants for mood and have been on a stable dose for over a month and meet the eligibility criteria for hot flash frequency and duration are eligible.
4. Women of childbearing potential, premenopausal women.
5. Other herbal supplements for any reason, including soy and soy supplements such as powders, pills and milk.
6. Diagnosis of irritable bowel syndrome, colitis, Crohns disease or any GI condition where the patient should not consume and/or has an intolerance/allergies to seeds or nuts.
7. Anticoagulant or anti-platelet (1 mg Coumadin for central line patency is allowed) therapy. Note: 81mg and below aspirin is allowed.
8. Anti-hypertensives, as flaxseed may potentiate this therapy.
9. Diabetes requiring oral or injectable anti-hyperglycemics.
10. Current (\leq last 4 weeks) treatment with anti-cancer therapies of any kind except trastuzumab and endocrine therapies are allowed (tamoxifen, aromatase inhibitors, raloxifene as defined in 3.21).

Pre-Study Parameters

1. H&P with performance status
2. FSH/estradiol (if required to determine menopause status)

